



Vitrex B.V.
% Genci Omari, Official Correspondent
Beaver-Visitec International, Inc.
500 Totten Pond Rd - 10 CityPoint
Waltham, Massachusetts 02451

Re: K182646

Trade/Device Name: Vitrex disposable laser probes, light fibers and Chandelier
Regulation Number: 21 CFR 886.4690
Regulation Name: Ophthalmic Photocoagulator
Regulatory Class: Class II
Product Code: HQB, HQF, MPA
Dated: March 18, 2019
Received: March 22, 2019

Dear Denise Kelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Malvina Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose,
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K182646

Device Name

VitreQ Disposable Laser Probes, 90° Directional Laser Probes, 90° Directional Illuminated Laser Probes, Light Fibers and Chandelier.

Indications for Use (Describe)

VitreQ Disposable Laser Probes, 90° Directional Laser Probes and 90° Directional Illuminated Laser Probes are intended for use in vitreoretinal surgery to perform endo-ocular laser photocoagulation treatments at operating wavelengths of 500nm to 900nm.

The 90° Directional Illuminated Laser Probes, Light Fibers and Chandelier are for illumination during ophthalmic surgery and should only be used with the light wavelength range of 425nm to 700nm.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

VitreQ Disposable Laser Probes, Light Fibers and Chandelier

Submitter of 510(k):

Company name: VitreQ B.V.
 Registration number: 3012037425
 Address: Seggelant-Noord 2, 3237 MG Vierpolders, The Netherlands
 Phone: +31 181 745090
 Fax: +31 181 478583
 Correspondent: JanKees Wouts
 Email: RA@vitreq.com

Device Name:

Device Trade Name: VitreQ Disposable Laser Probes, 90° Directional Laser Probes and (90°) Directional Illuminated Laser Probes
 VitreQ Disposable Light Fibers, Standard Light Fibers, Wide View Light Fibers, 45 Degree Shielded Light Fibers and Chandelier.
 Regulation Number: 21 CFR 886.4390
 Regulatory Name: Ophthalmic Photocoagulator
 Regulatory Class: II
 Product Code: HQF, HQB, MPA

Predicate Devices

Our device is substantially equivalent to the predicate device cited in the table below:

510(k)	Applicant	Device Name	Product Code	Claim
K121187	Katalyst Surgical, LLC	Katalyst Laser Probes & Illuminated Laser Probes	HQF, HQB, MPA	Predicate Device (primary)
K151604	Peregrine Surgical Ltd.	Peregrine 23 ga and 25 ga Adjustable Chandelier Illuminator	MPA	Predicate Device (secondary)

Description

The VitreQ Disposable Laser Probe is an ophthalmic instrument, which is used in posterior segment eye surgery and is appropriate for photocoagulation. The device can be connected to an ophthalmic laser generator, which is not a part of this application.

The VitreQ Disposable Laser Probe is introduced into the posterior segment of the eye through an incision or an ophthalmic entry port, after the vitreous is removed during vitreoretinal surgery.

The Disposable Laser Probe guides the laser energy to the intended surgical site to provide photocoagulation treatment. The laser energy intensity or power output is not controlled, altered or significantly reduced by the disposable laser probe. The laser spot size on the target tissue can be varied by altering the distance between the tissue and the probe tip.

To reach the target tissue in the periphery section of the eye the 90° Directional Laser Probe tip can be directed due to bending the metal tip. The angle of the tip in the most directed position is about 90°. An angled laser probe reduces the need of a strong indentation of the eye and is intended to prevent accidentally touching the crystal lens.

The VitreQ Disposable Laser Probes, 90° Directional Laser Probes and (90°) Directional Illuminated Laser Probes are constructed with an optical laser connector, a glass fiber optic covered by a protective sheath and one handle for surgeon manipulation, metal tubing is extending from the handle which penetrates the surgical site. The device is intended for single-use only.

The VitreQ Disposable Laser Probes can only be used with a medical laser at an operating wavelength range of 500nm to 900nm.

For the VitreQ Disposable Laser Probes, (90°) Directional Illuminated Laser Probe the functionality is combined with illumination. To achieve the illumination of the surgical site, the probe is constructed with an additional plastic fiber, which has a connector to attach the fiber to an ophthalmic light source, which is not a part of this application.

The VitreQ Disposable Light Fibers are constructed with a handle, the plastic illumination fiber, and the connector to attach the fiber to an ophthalmic light source. To match the connection to the ophthalmic light source, there are several reusable light source adaptors available.

The VitreQ (90°) Directional Illuminated Laser Probes, Light Fibers and Chandelier can only be used with the light wavelength range of 425nm to 700nm.

Indications for Use:

VitreQ Disposable Laser Probes, 90° Directional Laser Probes and (90°) Directional Illuminated Laser Probes are intended for use in vitreoretinal surgery to perform endo-ocular laser photocoagulation treatments at operating wavelengths of 500nm to 900nm.

The (90°) Directional Illuminated Laser Probes, Light Fibers and Chandelier are for illumination during ophthalmic surgery and should only be used with the light wavelength range of 425nm to 700nm.

Summary of technological characteristics

Comparison of identifications for Use

The indications for use of the VitreQ Disposable Laser Probes, Light Fibers and Chandelier are identical to the indications for use of the predicate devices.

The subject device and primary predicate device are both intended for use in vitreoretinal surgery to perform endo-ocular laser photocoagulation treatments at operating wavelengths of 500nm to 900nm.

Although the secondary predicate device is only used to support similar technology. Both, the subject device and secondary predicate device, are for illumination during ophthalmic surgery. The subject device is more specific with specification of the wavelengths.

Comparison of device characteristics

The table below shows the substantial equivalence with regards to the characteristics of the subject device and predicate device.

Characteristics	Subject Device			Predicate Device (primary)	Predicate Device (secondary)	SE Discussion
	Directional Laser Probes	Illuminated Laser Probes	Light Fibers & Chandelier	K121187 Laser Probes & Illuminated Laser Probes	K151604 23 ga and 25 ga Adjustable Chandelier Illuminator	
Laser Probe	Nitinol		Not applicable	Nitinol	Not applicable	Not applicable
Laser Optical Fiber	Glass		Not applicable	Glass	Not applicable	Not applicable

Characteristics	Subject Device			Predicate Device (primary)	Predicate Device (secondary)	SE Discussion
	Directional Laser Probes	Illuminated Laser Probes	Light Fibers & Chandelier	K121187 Laser Probes & Illuminated Laser Probes	K151604 23 ga and 25 ga Adjustable Chandelier Illuminator	
Illumination Fiber	Not applicable		PMMA Fluorinated Polymer Cladding	PMMA Fluorinated Polymer Cladding	PMMA Fluorinated Polymer Cladding	Not applicable
Handpiece	ABS			3D-printed Nylon	Acetal	Substantial Equivalent. Vitreq handpiece is made of ABS, it concerns a part which is not in contact with the patient
Laser Jacket	Thermoplastic rubber		Not applicable	Elastomer	Not applicable	Substantial Equivalent. Vitreq jacket is made from thermoplastic rubber, it concerns a part which is not in contact with the patient
Light jacket	Not applicable		LDPE/ EVA/ PVC	Unknown	PTFE	Substantial Equivalent. Vitreq jacket is made from EVA/PVC/LDPE, it concerns a part which is not in contact with the patient
Needle	Not applicable		Stainless Steel / MP35N	Not applicable	Stainless Steel	Substantial Equivalent. Vitreq needle is made from Stainless Steel/ MP35N, it is biocompatible. See Tab 15.
Laser connector	Nickel plated brass Stainless Steel		Not applicable	Nickel plated brass Stainless Steel	Not applicable	Not applicable
Light connector	Not applicable	Stainless Steel		Unknown	Acetal with Stainless Steel	Substantial Equivalent. Vitreq connector is from stainless steel only, it concerns a part which is not in contact with the patient
Laser Type	Solid state diode		Not applicable	Solid state diode	Not applicable	Not applicable
Laser Wavelength	500nm to 900nm		Not applicable	500nm to 900nm	Not applicable	Not applicable
Max Threshold of Laser Fiber	3 Watt		Not applicable	3 Watt	Not applicable	Not applicable
Transmission of Treatment Laser	99.8%		Not applicable	99.6%	Not applicable	Substantial Equivalent. The difference between predicate and subject device are negligible. See Tab 18.
Laser Power Efficiency	0.998		Not applicable	0.996	Not applicable	Substantial Equivalent. The difference between predicate and subject device are negligible.
Laser Output Power	500 ± 15% mW		Not applicable	500 ± 20% mW	Not applicable	Substantial Equivalent. The Vitreq device has more strict tolerances than the predicate device.
Laser Size	NA value between 0.1 and 0.2		Not applicable	NA value between 0.1 and 0.2	Not applicable	Not applicable. Bench testing is performed see Tab 18
Light Type	Not applicable	LED, Xenon or Mercury		Xenon or Mercury	Xenon or Mercury	Substantial Equivalent. Vitreq also tested the LED, which is currently state of th

Characteristics	Subject Device			Predicate Device (primary)	Predicate Device (secondary)	SE Discussion
	Directional Laser Probes	Illuminated Laser Probes	Light Fibers & Chandelier	K121187 Laser Probes & Illuminated Laser Probes	K151604 23 ga and 25 ga Adjustable Chandelier Illuminator	
						art technology. The values of Xenon and LED are substantial equivalent. Bench testing is performed see Tab 18.
Wavelength	Not applicable	425nm to 700nm		425nm to 700nm	425nm to 700nm	Not applicable
Transmission of Illumination Light	Not applicable	12.5 %	39%	Unknown	39%	Identical, transmission of illuminated laser probes is less than light fibers/ chandeliers

Substantial Equivalence Discussion

The VitreQ Disposable Laser Probes, 90° Directional Laser Probes and (90°) Directional Illuminated Laser Probes are intended for use in vitreoretinal surgery to perform endo-ocular laser photocoagulation treatments at operating wavelengths of 500nm to 900nm.

The (90°) Directional Illuminated Laser Probes, Light Fibers and Chandelier are for illumination during ophthalmic surgery and should only be used with the light wavelength range of 425nm to 700nm.

The VitreQ Disposable Laser Probes, Light Fibers and Chandelier make use of the same principle of operation, which is transmission of radiation energy through a fiber based on the principle of total reflection within a multimode fiber (consisting of a core and cladding).

The differences in technological characteristics are accompanied by information that demonstrates that the device is as safe and effective as the predicate device.

Design Differences:

The VitreQ Directional Laser probes have a different tip design same surgical result will be achieved.

The VitreQ light fibers have a different tip design, which decrease the hazard of phototoxicity, which is confirmed by test results according to standard ANSI Z80.36.

There are differences in available product sizes between the subject and predicate device, this is not related to safety and efficacy.

The subject and predicate device have a different handle design. Both solutions are considered equivalent to initiate movement of the tip. There are differences in shape and dimensions, which are considered related to the look and feel of the instrument.

The purpose of the jacket of the laser fiber and the optical fiber is identical. There are small differences in dimensions and material.

The lengths of the subject and predicate device are different, but the length of the device is not related to safety and effectiveness.

Reorientation of the subject and predicate device is based on a different principle. Providing a means to direct the device to the surgical site does not influence the safety and effectiveness but can improve performance and allow bimanual surgery to shorten the surgical intervention.

Differences in materials

The VitreQ handle, jackets (light and laser) and light connector have differences with regards to material, but these items are not a patient contact material.

Differences in performance (related to laser only)

The laser power output value of the VitreQ device and the predicate device are identical. The VitreQ device has more strict tolerances than the predicate device.

Differences in performance (related to illumination only)

VitreQ has tested Light Hazard Protection according to the FDA recognized standard ANSI Z80.36-2016. The predicate device delivers information in the Instructions for Use according to the standard ISO 15004-2, which is no longer FDA recognized.

Information to the user is provided according to standard ANSI Z80.36-2016.

Substantial Equivalence Conclusion

There are differences with regards to design, handle construction, materials, packaging, shelf life and labeling. These differences do not affect the similarity in principal technology, function and operational characteristics of the devices. As a result, it is determined that the VitreQ Disposable Laser Probes, Light Fibers and Chandelier is substantially equivalent to the predicate device.

Sterilization and shelf life

The VitreQ Disposable Laser Probes, Light Fibers and Chandelier have been successfully adopted to the validated Ethylene Oxide sterilization method. Sterilant residuals and bacterial endotoxins are kept below the allowable limits. A Shelf life study is performed to establish an expiration date of 5 years after sterilization.

Biocompatibility

The VitreQ Disposable Laser Probes, Light Fibers and Chandelier have been evaluated and tested for biological safety according to the standard ISO 10993-1 and the related FDA guidance for industry.

Performance Testing Summary

The VitreQ Disposable Laser Probes, Light Fibers and Chandelier have been tested to meet the product requirements and requirements from (safety) standards. Verification covers performance testing and human factors testing.

Conclusion

The VitreQ Disposable Laser Probes, Light Fibers and Chandelier were shown to be substantially equivalent to the predicate devices in intended use and fundamental technology and technological characteristics to the predicate devices.